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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,045	12/18/2000	Jacques Bauer	GEI-084	6820
20311	7590	03/04/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/720,045	BAUER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 16-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 16-31 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. The amendments to the claims contained in the response filed February 5, 2004 were not accurately marked with underlining and crossthroughs as required by 37 CFR 1.121(c). For example, at claim 4, line 3, "and" was inserted after "1,10-diol" without underlining, and "and/or" was deleted from between "1" and "10" in the phrase "1 10 bis" and was replaced with a comma without underlining and strikethrough. At claim 16, page 6 of the amendment, after line 4, the definition of "n" was omitted without strikethrough. At claim 16, page 6 of the amendment, line 9, a hyphen was inserted between "non" and "toxic" without marking. At claim 17, line 1, a semicolon was inserted after "with" without marking. At claim 18, line 1, and claim 19, line 1, "compositions" was changed to "composition" without marking. At claim 23, line 4, a comma was inserted after "atoms" without marking. At claim 25, line 8, "amine" was changed to "amino" without marking. At claim 26, line 3, a group in the formula is both underlined and struck through. At claim 26, after line 9, the step "reacting the latter with... (III)" was omitted from the claim without strikethrough. At claim 26, page 11, line 3, the new compound formula is not underlined.

Any future amendments to the claims should ensure that the amendment provisional of 37 CFR 1.121 are fully and accurately complied with. Any amendments after final rejection which do not comply with the amendment rules will not be entered.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

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The Sequence Listing filed March 28, 2003 was not accompanied by a statement that the sequence listing includes no new matter. See 37 CFR 1.821(g).

Correction is required.

The statement filed February 5, 2004 does not satisfy the above requirement because it does not given any identifying data for the paper and computer readable forms. For example, the statement does not refer to the paper and computer readable forms filed March 28, 2003.

Further, the statement that the “computer readable form diskette are identical” is unclear as to what is supposed to be identical to the computer readable form diskette.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of Figures 36-47 as required by 37 CFR 1.74. The amendment to the specification contained in the response filed February 5, 2004 refers only to Figures 1-35. Appropriate correction is required.

4. Claims 4 and 16-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush language of claim 4 is indefinite because “1,10-bis-(dihydrogenphosphate)” is not a compound of claim 21, and thus it does not appear that it can be an alternative to the first-named compound. The relationship between the “1,10-bis-(dihydrogenphosphate)” and the first-named compound is unclear. Claim 21 is indefinite because it provides two different definitions of the variable “n”. See lines 7-8. It is not clear which of the definitions controls. Claim 25, lines 1-12, recites process steps by which a compound of the formula recited at line 14 is to be obtained. However, the  $(CH_2)_q$  and the  $R_2$  groups which are present in the compound of line 14 are not present in any of the reactants used

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in the process steps, and the  $(\text{CH}_2)_n$  group which is present in the reactant of Formula III is not present in the product of formula IV. Further, while claim 25, line 6, recites the use of a  $\text{R}_2\text{OH}$  reactant, the intermediate product of the formula at line 9 does not contain a  $\text{R}_2$  group. Also, while claim 25, lines 6-7, recites that the alcohol moiety is to be acylated, the formula at line 9 shows that the amino group has been acylated and that the alcohol group has somehow been re-converted back to a free carboxylic group. Claim 25 is indefinite because it requires reaction “with a  $\omega$ -hydroxy, amino or thioamino acid of Formula III”; however, Formula III requires the presence of an OX group and does not permit the presence of an amino or thioamino group. At claim 25, the reactant of formula III shows the presence of an OX group, whereas the product of formula IV shows the presence of an AX group. It is not clear how one group has been converted to the other in the claimed process. At claim 25, the reactant at line 9 has a free carboxylic acid group, but after only a peptide condensation step, a product of formula IV is formed with an -OH group. It is not clear how the one group has been converted to the other in the claimed process. Claim 26 is indefinite because it refers to “the n and  $\omega$  blocking functions” of a compound of the recited formula. However, the formula at line 3 of the claim does not have any blocking functions. There is no antecedent basis in the claim for the phrase “the (q+1) amine function” at claim 26, line 5. The formula was amended to delete the (q+1) subscript. While claim 26, line 3, recites a reactant which comprises a  $(\text{CH}_2)_o$  group, neither the intermediate of formula III, the intermediate of formula IV, or the final product comprise a  $(\text{CH}_2)_o$  group. While claim 26, line 7, recites the use of a  $\text{R}_2\text{OH}$  reactant, the intermediate product of the formula at line 9 does not contain a  $\text{R}_2$  group. Claim 26, line 5, requires reduction of the free COOH group to  $\text{CH}_2\text{OH}$ . However, the intermediate of formula III has a free COOH group, and it is not clear

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how this group has been obtained in the claimed method. Claim 26, line 7, recites a hydrogenolysis step so as to free the terminal amine. However, the product of this step, having formula III, does not show a free terminal amine group. Claim 26 is indefinite because the step which indicates what is to be reacted in the presence of a peptide condensation agent is missing. Claim 26 is unclear because the  $(CH_2)_p$ ,  $(CH_2)_q$ , and  $R_2$  groups which are present in the compound of formula (IV) are not present in the reactant at line 3 or the reactant of formula III. The process steps of claims 25 and 26 require major revision.

5. Claims 16-19, 23, and 25-30 are objected to because of the following informalities: At claim 16, page 6 of the amendment, line 1, "chain-" should be deleted. At claim 17, line 1, "compositions" should be changed to "composition" so that claim terminology is consistent with that used in claim 16. At claim 17, line 1, the semicolon after "with" should be deleted. At claim 23, line 4, the comma after "atoms" should be deleted. At claim 25, lines 2-3, if the compound formula is to be written in a single line rather than structurally, then "-NH<sub>2</sub>-CH-" in the formula should be re-written as -CH(NH<sub>2</sub>)- so that it is clear how the amino group is to be attached to the remainder of the compound. At claim 26, line 2, a verb, probably "blocking", is missing from after "comprising". Applicants' insertion of "blocking" after "amine" in line 2 does not satisfy this objection because in this location, "blocking" does not serve as a verb. At claim 26, line 7, "the latter" appears to refer to the compound R<sub>2</sub>-OH rather than to the compound which results from the acylating step of lines 5-7. For similar reasons, the phrase "the latter" at claim 26, page 11, line 5, should also be clarified. Appropriate correction is required.

6. Applicant is advised that should claim 5 be found allowable, claim 4 may be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

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are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference between claims 4 and 5 appears to be the presence of “and” at claim 4, line 3. It is not clear how, if at all, this may affect the scope of claim 4 (see also the above rejection under 35 U.S.C. 112, second paragraph).

7. Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 4 and 16-31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action.

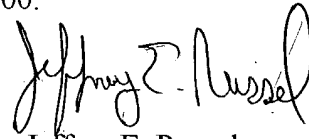
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

February 26, 2004